REMARKS

Applicants thank the Examiner for the time taken to examine the application. Claims 1-11, 14-17 and 19-28 are pending in this application. Independent claims 1 and 15 have been amended. Dependent claims 16 and 17 are amended to correct grammatical or typographical errors. Applicants respectfully requests reconsideration of the pending claims in view of the above amendments and the following remarks.

Rejections Pursuant to 35 U.S.C. §101

The Examiner has rejected all of the pending claims (claims 1-11, 14-17 and 19-28) pursuant to 35 U.S.C. §101 as not falling within one of the four statutory categories of invention. Specifically, the Office Action cites Supreme Court precedent and recent Federal Circuit decisions as indicating that a statutory "process" under 35 U.S.C. 101 must (1) be tied to another statutory category (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or material) to a different state or thing. The Office Action further states that the claimed methods "neither transform underlying subject matter nor positively tie to a machine that accomplishes the claimed method steps," and that, for example, claim 1 "would be reasonably interpreted as a series of steps completely performed mentally, verbally or without a machine."

Applicants believe that, under the USPTO's newly developed interim guidelines regarding patentable subject matter and the applicable case law, the claims in their prior form were directed to patentable subject matter. Regardless, the independent claims have been amended to more clearly comply with the interim guidelines and the applicable law.

35 U.S.C. §101 states, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." In interpreting that law, the Supreme Court has reflected that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Diamond v. Diehr*, 450 U.S. 175, 182 (1981). The Court went on to reason:

> *That a process may be patentable, irrespective of the particular form of the instrumentalities used, cannot be disputed.* ...A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing. *If new and useful, it is just as patentable as is a piece of machinery.*

Diamond v. Diehr, 450 U.S. 175, 182-184 (1981) (citing *Cochrane v. Deener,* 94 U.S. 780, 787-788 (1877) (emphasis added).

Applicants have amended independent claims 1 and 15 to ensure that all of the pending claims meet both aspects of the test for statutory subject matter cited by the Examiner. In other words, as amended, all of the claims are "new and useful" processes that (1) are tied to a machine in the form of a computer system, and (2) transform the underlying subject matter.

First, claim 1 is a method of predicting a fracture path in bone using a computer system, and is thus tied to patentable subject matter. The elements of claim 1 make clear that this is not merely an abstract idea or mental exercise, but that various steps of the method are performed by the computer system. Such computer systems are described throughout the specification, including at paragraphs 51, 78, 85-87, 94-96, 106, 111-123, 129, 136, 189, 236, 237, 242, 309, 330 and 331, which, among other things, describe computers, computational units, computer networks and other systems that can be used in various embodiments alone or in combination.

Second, claim 1 claims subject matter that is transformed. For example, claim 1 recites that image data of the bone is used to generate a composite parameter map of the two or more parameters that were analyzed. As such, claim 1 claims "a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing" as required by Supreme Court precedent.

Independent claim 15 similarly meets both prongs of the test for patentable subject matter cited in the Office Action. First, claim 15 is a method of predicting the risk of fracture of bone using a computer system, and is thus tied to patentable subject matter. The elements of claim 15 make clear that this is not merely an abstract idea or mental exercise, but that various steps of the method are performed by the computer system. Such computer systems

are described throughout the specification, including the paragraphs discussed above in conjunction with claim 1.

Second, claim 15 claims subject matter that is transformed. For example, claim 15 recites that image data of the bone is used to create one or more parameter maps that are used to generate a biomechanical model. As such, claim 15 claims "a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing" as required by Supreme Court precedent.

All of the other pending claims (claims 2-11, 14, 16, 17 and 19-28) are patentable for at least the same reasons as independent claims 1 and 15, because they each depend from those claims. Thus, Applicants submit that all of the claims are now in allowable form.

CONCLUSION

All pending claims are believed to be in a form suitable for allowance. Therefore, the application is believed to be in a condition for allowance. The Applicants respectfully request allowance of the application. The Applicants also request that the Examiner contact the undersigned, if it will assist further examination of this application.

Applicants petition for a three-month extension of time. In the event that a further extension is needed, this conditional petition of extension is hereby submitted. Applicants request that deposit account number 19-4972 be charged for any fees that may be required for the timely consideration of this application.

Respectfully submitted,

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